K 120510

JUL 1 9 2013

510(k) SUMMARY
Syneron Medical Ltd's Transcend System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: July 12, 2013

Name of Device
Transcend System

Common or Usual Name
Laser surgical instrument for use in general and plastic surgery and in dermatology

Classification Name

NUV – Laser surgical instrument for use in general and plastic surgery and in dermatology
GEI – Electrosurgical, Cutting & Coagulation & Accessories

Predicate Devices

Syneron VelaShape system (K071872)
Alma Lasers Accent UniForm Massager Handpiece (K082622)

Intended Use / Indications for Use

The Transcend is indicated for temporary reduction in circumference of the abdomen.

Technological Characteristics

The Syneron Transcend is an optical energy in the Infra Red range and a radio frequency of 1 MHz powered system. The device consists of a console and two applicators that deliver electromagnetic energy (IR light and Radio Frequency) and vacuum to treated

tissue for the temporary reduction in circumference of the abdomen.

The Transcend console includes a control panel, power supply modules, vacuum pump, main Digital Signal Processor, umbilical cable and an adaptor- for connecting the two available applicators, two applicators and two LCD touch-screens.

Performance Data

The Transcend system performance was evaluated by lab tests and a supportive clinical study. Lab Testing included electromagnetic compatibility, electrical safety, Biocompatibility, and software verification and validation. All performance testing demonstrates that the Transcend System performs according to specifications and functions as intended. The Transcend fulfills the requirements for safety and efficacy.

The Transcend was evaluated in two prospective, multicenter studies for the intended use of abdomen circumference reduction, including over 100 subjects. Efficacy was evaluated based on the change in abdomen circumference from baseline to post treatment as evaluated at 1 week, 1 month, and 3 months following the last treatment session. Measurements were performed for both treated and control subjects. No serious adverse events related to the treatment were reported. The clinical study data for the Transcend subjects demonstrated significant reduction in waist circumference. The clinical data support the substantial equivalence of the Transcend system for the indication of temporary reduction in circumference of the abdomen. Additional data from clinical experience outside the United States further supports the performance of the Transcend for the intended use.

Substantial Equivalence

The Transcend is very similar to the VelaShape system and the Accent UniForm Massager Handpiece. The Transcend has similar indications, technological characteristics, and principles of operation as its predicate devices. Performance data demonstrate that the differences between the Transcend and the predicates do not adversely impact its performance. The efficacy of the Transcend was evaluated by a clinical trial to support the new indication for use.

Thus, the Transcend is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 19, 2013

Syneron Medical, Ltd.
% Mr. Sam Wade
Industrial Zone, Tavor Building
P.O. Box 550
Yokneam Illit, Israel 20692

Re: K120510
Trade/Device Name: Transcend System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 17, 2013
Received: May 17, 2013

Dear Mr. Wade:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120510

Device Name: TRANSCEND

Indications For Use: The Transcend is indicated for temporary reduction in circumference of the abdomen

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.07.12 14:07:54 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K120510